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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

LB 4/3/97

Certified/Return Receipt Requested

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
Lenexa, Kansas 66214-3340

Telephone: (913) 752-2100

April 2, 1997

WARNING LETTER

William B. Smith, Jr., President
WB Smith Feed Mill, Inc.
9201 South Hatchery Road
Columbia, Missouri 65203

Ref. # - KAN-97-013

Dear Mr. Smith:

An inspection of your medicated feed mill operation, located at the above address, conducted by an investigator from this office on March 11, 1997, found significant deviations from Current Good Manufacturing Practice (CGMP) regulations for Medicated Feeds (21 CFR, Part 225). Such deviations cause medicated feeds being manufactured at this facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (Act).

Our investigation found: 1) failure to record and maintain a daily drug inventory which would include manufacturer's lot numbers, quantity on hand, amounts used, and batches of feeds drugs were used in; 2) failure to properly store open containers of drugs, in that there is no manufacturer's lot numbers recorded for the drugs placed into barrels; 3) failure to have production records checked and signed/initialed by a responsible person at the end of each production day; 4) failure to have the drug scale calibrated on an annual basis.

The above is not intended to be an all-inclusive list of violations. As a manufacturer of medicated and non-medicated feeds, you are responsible for assuring that your overall operation and the products you manufacture are in compliance with the law. At the conclusion of the inspection Form FDA 483, Inspectional Observations, was issued to and discussed with Martin B. Smith, Vice President. This form is a comprehensive listing of deviations observed by the investigator during the inspection. A copy of this form is enclosed for your information.

You should take prompt action to correct the noted violations, and you should establish procedures whereby such violations do

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not recur. Failure to promptly correct these violations may result in regulatory and/or administrative sanctions. These sanctions include, but are not limited to, seizure, injunction, and/or notice of opportunity for a hearing on a proposal to withdraw approval of your facility license under Section 512(m)(4)(B)(ii) of the Act and 21 CFR 514.115(c)(2). (This letter constitutes official notification under the law.) Based on the results of the March 11 inspection, evaluated together with the evidence before FDA when the license was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of medicated feeds are inadequate to assure and preserve the identity, strength, quality, and purity of the new animal drugs therein. This letter notifies you of our findings and provides you an opportunity to correct the above deficiencies.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, to inform us of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. You may address your reply to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

W. Michael Rogers
District Director
Kansas City District

Enclosure - Form FDA 483